

Functional and oncological outcomes after transanal local excision for rectal cancer. A prospective study

G. LUGLIO, R. TARQUINI, L. SIVERO, M. C. GIGLIO, C. DE WERRA
C. FORMISANO, D. D'ANTONIO, G. BENASSAI, L. BUCCI

*Department of General, Geriatric
Oncologic and Advanced Technologies
Federico II University of Naples, Naples, Italy*

Aim. Surgery for rectal cancer is impaired by a significant risk of perioperative morbidity, urinary and sexual dysfunction due to nerve injuries and, obviously, the possibility of a temporary or even a permanent stoma. In order to mitigate the sequelae of such a major surgery, trans-anal local excision has been proposed in selected cases to treat rectal cancer. Aim of this prospective study is to investigate which patients might get a benefit from this less invasive treatment, evaluating both oncological and functional results.

Methods. A prospective database has been maintained in our Surgical Coloproctology Unit, registering all cases of rectal cancers that have been treated from 2000 to date. 26 patients from 2000 to 2005 have been treated with local excision; mean age was 76. Each patient has been followed-up for 5 years. All patients were preoperatively staged with endorectal ultrasound; elderly patients, unfit for surgery or refusing major surgery or the possibility of a stoma, with a superficial T1 tumor were mostly considered eligible for local excision. 5-year local and systemic recurrence rate, overall survival and functional outcomes have been assessed.

Results. Sixteen patients were staged as T1 rectal cancer with superficial invasion of the submucosa at the endorectal ultrasound. Two patients had a T2 cancer and refused major surgery or other preoperative treatments. Two patients had a T1 tumors which appeared to deeply infiltrate the submucosa; six patients had a T2 tumors and refused surgery or were considered unfit for it: all of them were offered to have a preoperative radiotherapy plus a local excision. None of the 16 T1 patients had a 5-year local recurrence, despite one of them had a systemic recurrence. Both patients with a T2 tumor and not pretreated with radiotherapy had a local recurrence. One of the T1 and one of the T2 patients pretreated with radiotherapy had a systemic but not local recurrence. Only one patient who was radiated experienced a worsening of a preexisting fecal incontinence.

Conclusion. Transanal local excision of rectal cancers should be offered only in highly selected, low risk, T1 tumors. People with higher risk cancers, unfit or refusing surgery, should at least be treated with preoperative radiotherapy plus local excision.

KEY WORDS: Microsurgery - Rectal cancer - Rectal neoplasms.

The gold standard treatment for middle and low rectal cancer is represented by the TME (Total Mesorectal

Excision). Soon, after its first description,^{1, 2} this technique has proved to be able to achieve a dramatic reduction in local recurrence till 4%.³ This major surgery, however, is impaired by a high risk of perioperative morbidity, urinary and sexual dysfunction⁴ due to nerve injuries and, obviously, the possibility of a temporary or even a definitive stoma, as sometimes sphincter saving procedures are not feasible. In order to mitigate the sequelae of this surgery, transanal local excision and transanal endoscopic microsurgery (TEM),⁵ might be considered as feasible alternatives in selected cases. Local excision is a local treatment which allows to take out a small rectal tumor, through a circumferential, full-thickness resection, without the need to enter the abdomen and resect the whole rectum with its lymphatic drainage; obviously, it's a sphincter saving procedure as well and no coloanal anastomosis is required, thus avoiding the "anterior resection syndrome" and a poor quality of life.⁶⁻¹¹ On the other hand, big concerns still arise from considering the oncologic safety of local excision, and clear guidelines from literature do not exist.

Aim of this prospective study was to investigate which patients might get a benefit from this less invasive treatment, evaluating both oncological and functional results.

Materials and methods

A prospective database has been maintained in our Surgical Coloproctology Unit, registering all cases of rectal cancers that have been treated from 2000 to date. 26 patients from 2000 to 2005 have been treated with local excision, and have been enrolled in this study. Mean age was 76; 16 were female. Each patient has been followed-up for 5 years.

All patients were preoperatively staged with clinic examination, rigid rectosigmoidoscopy, CT-scan, CEA, CA 19.9 and endorectal ultrasound. Local staging, in partic-

Corresponding author: G. Luglio, Dipartimento Chirurgia Generale, Geriatrica, Oncologica e Tecnologie Avanzate, Università degli Studi di Napoli Federico II, Napoli, Italy. E-mail: gaetano.luglio@gmail.com

ular, was achieved through endorectal ultrasound (BK-Medical, 1850, 10 MHz), with the aim to analyze the depth of invasion through the rectal wall and in particular the level of submucosa invasion (SM1, SM2, SM3), depending on the invasion of the superficial or the deepest part of submucosa.

After a detailed informed consent, patients underwent local excision if they were staged as a T1 superficial rectal tumor, not more than 3 cm in diameter and less than 7 cm far from dentate line; this technique was also performed in elderly patients, unfit for surgery or refusing major surgery or the possibility of a stoma. With regard to oncological outcomes 5-year local and systemic recurrence rate and overall survival have been assessed. Functional outcomes were assessed using the Wexner Incontinence score,¹² which is a clinical questionnaire which was administered before surgery and six months after surgery. Short-term (30-day) postoperative major morbidity was also assessed, using the Dindo-Clavien morbidity system.¹³

With regard to the surgical technique we use to perform the local excision using a Parks retractor; the lesion is circumferentially marked by cautery and sometimes vicryl stitches are passed at the four cardinal points in order to get a kind of parachute. The most important aspect of the technique, however, is the "full thickness" resection, that means that all the rectal wall layers adjacent to the lesion need to be excised till the mesorectal fat: this will allow to consider the specimen at least as a "total biopsy", for further histologic consideration.

Results

Sixteen patients were staged as T1 rectal cancer with superficial invasion of the submucosa at the endorectal ultrasound. Two patients had a T2 cancer and refused major surgery or other preoperative treatments. Two patients had a T1 tumors which appeared to deeply infiltrate the submucosa; six patients had a T2 tumors and refused surgery or were considered unfit for it: these latter 8 patients were offered to have a preoperative radiotherapy plus a local excision.

With regard to oncological outcomes we found that: none of the 16 T1 patients had a 5-year local recurrence, despite one of them had a systemic recurrence. Both the two patients with a T2 tumor and not pretreated with radiotherapy had a local recurrence. One of the T1 and one of the T2 patients pretreated with radiotherapy had a systemic but not local recurrence.

Summarizing the oncological outcomes, our cohort showed a 7.7% local recurrence rate, a 19.2% overall recurrence rate and a 80.7% overall survival rate.

Regarding major morbidity we had only one patient who experienced a pelvic abscess and was treated with a pelvic drainage plus colostomy.

Functional outcomes were assessed using the Wexner incontinence score: mean preoperative score was 4.2 and mean postoperative score was 5.1; this difference was not statistically significant. We basically found only one patient who experienced a worsening of a preexisting fecal

incontinence; this patient had a preoperative radiochemotherapy.

Discussion

Major surgery for rectal cancer with TME led to better oncological outcomes with a clear reduction of local recurrence. Postoperative quality of life, however, still remains a big issue to face. Radical surgery, in fact, is impaired by a high rate of nerve injuries, which compromises sexual and urinary function. More, the colo-anal anastomosis shows a high incidence of the so called anterior resection syndrome, with high stool frequency, soiling, incontinence, urgency. Finally, sometimes the tumor is too low for a sphincter saving surgery and in those cases the abdominoperineal resection is the only alternative, with the need of a permanent colostomy. The idea of local excision for rectal cancer lays on the possibility to treat really early rectal tumor, with no lymph-nodes in the mesorectum, for which radical surgery with TME, may represent an overtreatment. Thus, a big effort has been made to predict situations in which the probability of finding metastatic nodes in the mesorectum is high. Several criteria have been described to discriminate "low" and "high risk" rectal tumor. Nascimbeni *et al.*^{14, 15} from Mayo Clinic, show how a different depth of invasion of the submucosa layer (upper, middle or lower third), which they call Sm1, Sm2 or Sm3, correlates with a different risk of finding metastatic nodes in the mesorectum, which varies from 3% for Sm1 tumor to 23% for Sm3 tumor. The same authors also show how the risk of mesorectal nodes involvement improve in lower third rectal cancer, in high grade tumor and in those cases in which a lymphovascular invasion has been demonstrated. Other than this study from Mayo Clinic, two more big studies, one from Sloan-Kettering¹⁶ and the other one from Cleveland Clinic,¹⁷ point out how local excision for rectal cancer is impaired by a high risk of local recurrence and poor oncologic outcomes; these results are also more frustrating thinking about we are talking about T1, early tumor. These authors also advocate the importance, other than of bigger randomized study, of very good selection criteria, who might help finding those subgroups of "low risk" patients for whom local excision can be considered a safe alternative. Endreseth and the Norwegian rectal cancer group¹⁸ clearly demonstrate that local excision for rectal cancer leads to a higher local recurrence rate together with a reduced overall survival compared with major surgery. On the other hand, some evidence arise to show how local excision can lead to good oncological outcomes, other than in low risk T1 patients, also in patients who were preoperatively treated with chemoradiotherapy, even if T2 or T3. Callender *et al.*,¹⁹ show how in selected, "small", T3 tumors, which were treated with preoperative chemoradiotherapy, results in terms of local recurrence, disease free survival and overall survival do not significantly differ from the major surgery with TME. A US trial by ACOSOG, the Z6041 trial,^{20, 21} is currently investigating the role of local excision for T2 N0 rectal cancer, treated with preoperative chemoradiother-

no rifiutato l'idea di un intervento maggiore e la possibilità di una stomia definitiva, pazienti con cancro T1 iniziale, sono stati considerati eleggibili per una escissione locale. I tassi di recidiva locale e sistemica a 5 anni, la sopravvivenza globale e i risultati funzionali sono stati valutati.

Risultati. Sedici pazienti sono stati stadiati come cancro T1 iniziale. Due pazienti avevano un cancro T2 e hanno rifiutato la chirurgia maggiore. Due pazienti avevano un tumore T1 con infiltrazione profonda della sottomucosa; sei pazienti avevano un tumore T2 e rifiutarono la chirurgia maggiore. Nessuno dei 16 pazienti T1 hanno avuto una recidiva locale a 5 anni; 1 paziente ha mostrato recidiva a distanza. Uno dei pazienti T1 and uno dei pazienti T2, pretrattati con radioterapia, hanno avuto una recidiva sistemica ma non locale. Un paziente irradiato ha riportato un peggioramento di una preesistente incontinenza.

Conclusioni. L'escissione locale transanale del cancro del retto dovrebbe essere offerta solo a pazienti altamente selezionati, a basso rischio istologico, con stadio T1. Pazienti con tumori a più alto rischio, che non sono idonei o rifiutino la chirurgia maggiore, dovrebbero almeno essere pretrattati con radioterapia seguita da escissione locale.

Conclusions

References

Riassunto

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Metodi. Un database prospettico è stato mantenuto nella nostra Area Funzionale di Colonproctologia Chirurgica dal 2000 ad oggi. Ventisei pazienti sono stati trattati mediante escissione locale; età media 76 anni. Ogni paziente è stato seguito per 5 anni. I pazienti anziani, non idonei a chirurgia maggiore o che han-

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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